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UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark Office  
ASSISTANT SECRETARY AND COMMISSIONER  
OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

Ronald L. Wilson, Director  
Health Assessment Policy Staff  
Office of Health Affairs (HFY-20)  
Food and Drug Administration  
5600 Fishers Lane, Room 11-44  
Rockville, MD 20857

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Dear Mr. Wilson:

The attached application for patent term extension of U.S. Patent No. 4,621,077, which issued November 4, 1986, was filed on November 21, 1995, under 35 U.S.C. § 156.

The assistance of your Office is requested in confirming that the product identified in the application has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use. Since a determination has not been made whether the patent in question claims a product which has been subject to the Federal Food, Drug and Cosmetic Act, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 U.S.C. § 156(d)(2)(A).

Our review of the application to date indicates that the subject patent would NOT be eligible for extension of the patent term under 35 U.S.C. § 156, since the patent does not claim an approved product, a method of using of an approved product, or a method of manufacturing an approved product as required by 35 U.S.C. § 156(a).

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